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Position Paper

Identifying critical steps towards improved access to innovation in cancer care: a European CanCER Organisation position paper



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Abstract In recent decades cancer care has seen improvements in the speed and accuracy of diagnostic procedures; the effectiveness of surgery, radiation therapy and medical treatments; the power of information technology; and the development of multidisciplinary, specialist-led approaches to care. Such innovations are essential if we are to continue improving the lives of cancer patients across Europe despite financial pressures on our healthcare systems. Investment in innovation must be balanced with the need to ensure the sustainability of healthcare budgets, and all health professionals have a responsibility to help achieve this balance. It requires scrutiny of the way care is delivered; we must be ready to discontinue practices or interventions that are inefficient, and prioritise innovations that may deliver the best outcomes possible for patients within the limits of available resources. Decisions on innovations should take into account their long-term impact on patient outcomes and costs, not just their immediate costs. Adopting a culture of innovation requires a multidisciplinary team approach, with the patient at the centre and an integral part of the team. It must take a whole-system and whole-patient perspective on cancer care and be guided by high-quality real-world data, including outcomes relevant to the patient and actual costs of care; this accurately reflects the impact of any innovation in clinical practice. The European CanCer Organisation is committed to working with its member societies, patient organisations and the cancer community at large to find sustainable ways to identify and integrate the most meaningful innovations into all aspects of cancer care.

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1. Introduction

Over the last two to three decades, the field of cancer has seen improvements in the speed and accuracy of diagnostic procedures [1], the effectiveness of surgery [2–4], radiation therapy [5,6] and medical treatments [7,8] and the power of information technology [9]. Development of clinical support roles—such as those of specialist oncology nurses and of multidisciplinary, specialist-led approaches to care—have also played an important role in improving the care offered to cancer patients.

Investment in all these innovations is critical if we are to continue to improve the lives of cancer patients across all age groups in years to come. However, there is growing evidence of inequalities in, and complex barriers to access to, many innovations in Europe, as healthcare systems are increasingly challenging their costs, and out-of-pocket payments for cancer care are growing [10,11].

Although much of the literature and policy debate focuses on inequalities in access to anticancer medicines [12,13], significant inequalities also exist for other aspects of cancer care. Within this context, it is critical to balance investment in innovation with the need to ensure the sustainability of healthcare budgets, and this is a global concern [14–16].

In all countries, notions of innovation and value are intrinsically linked. We need to apply more scrutiny to the way we deliver care today, be ready to remove or discontinue practices or interventions that are inefficient, and be forward-thinking to prioritise innovations that may deliver the best outcomes possible for patients with the resources at hand. Implementation of innovations also needs to follow a structured pathway, and practices

should be adapted to accommodate them. Greater transparency is needed on prices and pricing policies, as has been called for by the European Cancer Leagues Task Force for Equal Access to Cancer Medicines. This being said, investment decisions on innovations should consider the long-term impact of innovations on patient outcomes and costs, not just their immediate costs.

All health professionals have a key responsibility to help achieve this balance. Within this context, this article offers a multidisciplinary perspective on how we can responsibly and sustainably encourage access to the most meaningful innovations for cancer patients in years to come whilst improving on existing practice and decreasing waste and inefficiencies across all aspects of cancer care. It was developed by the European CanCer Organisation (ECCO) with input from its member societies and the ECCO Patient Advisory Committee and is intended as the basis for future actions to be taken by relevant health professionals. These actions will be developed into an action plan in the next few months.

2. How do we define innovation in cancer care?

It may be argued that the term ‘innovation’ has been over-used in recent years and is usually thought of simply as ‘something new’ [18,19]. However, ‘newer’ is not necessarily better than older alternatives, and in reality what constitutes an innovation is more nuanced. Innovation can take place within any aspect of cancer care. It does not have to be complex, or expensive; simple interventions may often have the greatest impact on improving patient care. In addition, meaningful progress often occurs over time, as a result of a series of

incremental changes which, if taken in isolation, may not necessarily be transformative in their own right.

It is also critical to recognise that innovation is an evolving concept and must keep pace with our growing understanding of cancer and treatment expectations. For example, drug development models need to consider expected patterns of relapse and disease evolution to make sure that we are providing patients with the most appropriate course of treatment and not simply making decisions, one treatment at a time.

A definition of innovation that transcends these complexities is that it is any intervention within the care pathway that makes a meaningful difference to patients. With this definition in mind, member organisations of ECCO have made suggestions as to what aspects of cancer care represent the most meaningful innovations in their view and which practices should be considered as obsolete as they do not offer benefits to patients (see Table 1). These suggestions will be discussed and prioritised as a next step in this initiative by ECCO and its member organisations.

3. How does one measure the value of innovation?

Defining the value of an innovation requires a comprehensive assessment of its impact on patient outcomes, quality of life, quality of care and costs across the system.

The necessary starting point to the measurement of value of any innovation is to determine whether it offers real benefits to patients. Over the past few years, the European Society for Medical Oncology (ESMO), American Society of Clinical Oncology, European Society for Radiotherapy and Oncology (ESTRO) and other professional societies have called for a more consistent approach in the evaluation of new treatments and have proposed new measures aimed at capturing the real benefit of anticancer medicines and other technologies [20–22]. For example, ESMO's Magnitude of Clinical Benefit Scale (ESMO-MCBS) aims to 'help frame the appropriate use of limited public and personal resources to deliver cost-effective and affordable cancer care' [20]. The ESMO-MCBS is an important innovative instrument but is based solely on data from clinical trials, without consideration of costs [23]. Other scales include costs [24], however in Europe these vary from country to country. The ESMO-MCBS was initially developed without input from patients [25].

These limitations point to the need to consider the value of new interventions from the patient's perspective, giving adequate weight to quality of life and progression-free survival, and not only overall survival, and with input from all stakeholders.

Real-world data (from registries, large databases and big data initiatives) are part of the continuum of clinical research. They are key to determining whether benefits observed in clinical trials are also seen in unselected patient

populations in real-world settings and to understanding the impact of a given innovation on patient outcomes. Real-world data should also include the full costs of care.

Real-world data are very important for surgical techniques and medical devices, for which typically the data is much scarcer at the time of regulatory approval than for medicines. The IDEAL collaboration (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the Quality of Research in Surgery) has recommended that real-world data on the efficacy and safety of any new surgical procedure [26] or medical device [27,28] should be collected as soon as it is introduced into clinical practice, to guide clinical guidelines and improve the use of these procedures in clinical practice.

Real-world data are particularly critical in the case of rare adult cancers and paediatric cancers, as small patient numbers may limit the potential to gather sufficient evidence within traditional clinical trial settings. They are also a key component of 'coverage with evidence' schemes increasingly being used for new anticancer medicines, particularly 'breakthrough innovations' that are approved on the basis of early-stage trial data through accelerated approval schemes. These medicines may be granted provisional reimbursement based on early clinical trial data, on the condition that this decision is to be reviewed, and access potentially expanded, at a later timepoint once real-world data on the impact of this intervention are available.

4. What are barriers to the development and uptake of innovation?

Barriers may occur at different stages: research and clinical trials → regulatory approval (European Medicines Agency [EMA] and national) → national and regional access decisions (health technology assessment [HTA] or pricing and reimbursement) → uptake into local practice.

4.1. Research and clinical trials

There are numerous barriers to the development of innovative medicines, diagnostics and technologies during the research stage (e.g. in clinical trials), which contribute to delaying individual patients' access to innovations in areas of high unmet needs. These barriers delay the generation of meaningful data and knowledge from clinical research as well as the publication of research findings, leading to delays in the time it takes for an innovation to be adopted post-approval into clinical practice. Barriers in research often result from the absence of collaboration across disciplines and between different layers of healthcare provisioning (e.g. primary care, community oncology care, hospitals and academic centres), as well as insufficient information provided to patients and healthcare professionals about ongoing and completed research. Further barriers exist

Table 1

Defining areas of innovation and obsolescence across the cancer care spectrum.

Aspect of care	Areas of innovation	Examples of obsolescence
Psycho-oncology [30]	Routine psychosocial distress screening using validated self-report measures to identify cancer patients who should be referred to psychosocial services	Reliance solely on clinician observations or patient requests to identify cancer patients who should be referred to psychosocial services
Oncology nursing [46,47]	Increasing trained oncology nursing services in all European countries	Lack of appropriate and specific funding for trained oncology nurses
Supportive care and rehabilitation	Providing adequate and appropriate supportive treatments over the entire course of care Assessing the impact of treatment side-effects (physical, emotional, cognitive, sexual and nutritional) and develop a rehabilitation/survivorship plan to address and reduce those symptoms and problems	Insufficient supportive care leading to worse patient outcomes
Genetics [7]	Improved understanding of predisposition factors and use of these data to better characterise a tumour's aetiology and adapt therapy where supported by evidence	
Pathology [1,7,48]	Identification of molecular markers of prognostic or predictive value using various methodologies Quality control of pathology Research-based 'liquid biopsies' for characterising and monitoring tumours	Decision-making without use of such tools, when adequately recognised by scientific evidence
Monitoring [49]	Use of advanced imaging techniques to define disease extent and tailor treatment	Unjustified staging examinations Unjustified follow-up procedures
Adjuvant treatment [5,50]	Defining the need for long-term treatment versus shorter treatments Development of adjuvant treatments in specific biologically defined patient subsets Further exploration of how neo-adjuvant treatment results could be appropriately used to select adjuvant treatment and therefore avoid 'blind' adjuvant treatments	Studies that are not based on the present understanding of the biology of various tumour subtypes
Surgery [51–53]	Optimisation and standardisation of cancer surgery with educational programmes and quality assessment e.g. introduction of total mesorectal excision (TME) in colorectal cancer surgery Technological advances: e.g. minimally invasive surgery and interventional radiology to reduce short- and long-term negative outcomes When a new procedure is of proven benefit, make it accessible and develop centre expertise to ensure its appropriate use	Surgery performed in multiple low-volume centres with inadequate demonstration of expertise and quality results
Radiation therapy	Development of radiation therapy facilities according to standards supported by ESTRO, with image-guided radiation therapy, modulated and adaptive techniques and specific particle therapy facilities When a new procedure is of proven benefit, make it accessible and develop centre expertise to ensure its appropriate use	Radiation therapy performed in multiple low-volume centres with inadequate demonstration of expertise and quality results
Medicines [20]	Development of the use of the ESMO evaluation system (ESMO relative value scale) to prioritise medicines of greatest benefit to patients	Use of local scoring systems to decide whether or not to include a given medicine in a formulary
Geriatric oncology [54]	Screening for frailty and using geriatric assessment to stratify older populations with cancer and adjust treatment accordingly	Using civil or chronological age as a threshold for making strategic decisions related to a patient's care
Paediatric oncology [55,56] (also valid in adult treatment)	Accelerated and early access to innovative therapies during their development Novel immunotherapeutic approaches and medicines targeting epigenetics Novel functional and statistical tools to assess objective response and long-term survival benefit Standardised assessment of toxicity with emphasis where possible on patient-reported outcomes Transparent and obligatory patient-oriented long-term outcomes assessment	Repeating old and toxic therapies without any attempt to improve practice based on knowledge of molecular pathways and their function in different cancers Use of new therapies based on 'single-case evidence', as opposed to multicentre clinical trials—as was the case with haematopoietic stem cell transplantation years ago

Table 1 (continued)

Aspect of care	Areas of innovation	Examples of obsolescence
Big data [57,58]	Facilitate the exchange of ‘big data’ among different European countries in order to ameliorate, among other things, the quality of overall therapy	Perpetuation of siloed, disjointed health information systems and lack of cohesive solutions across different settings of care
Registries [59–62]	Making cancer registries an obligatory part of Europe-wide registration of any cancer type Use of epidemiological data to evaluate different practices and outcomes—to drive future treatment plans towards the most effective practices	Lack of such an approach—resulting in perpetuation of ineffective practices that could have been identified through appropriate data and research
Care planning [63,64]	Shaping future services in response to national cancer experience surveys of people living with cancer	Lack of multidisciplinary decision-making and out-of-date uni-disciplinary attitudes Lack of role development opportunities for the cancer workforce. These are necessary to respond to rising demand and patient expectations
Professional education [45]	Knowledge transfer across all relevant disciplines to apply novel techniques in diagnostics and treatment Professional education programmes to extend knowledge to all relevant specialities of: <ul style="list-style-type: none"> • the principles of risk assessment for acute complications • the principles of risk assessment for long-term outcomes and sequelae of treatment Development of a Europe-wide qualification and certification system in oncology—e.g. in the form of cross-border educational programmes—with transparent standards for quality assessment Extending knowledge to all health professionals involved in cancer care that health education, physical activity and lifestyle should be implemented to improve cancer care and quality of life for patients	
Clinical research [43,44]	New models of clinical studies developed in cooperation with population-based registries New types of access platforms where single cohort patients can be benchmarked to contemporary real-life patients New partnerships between academia/government and industry to allow <ul style="list-style-type: none"> • more ‘risky’ treatment arms in the design of registration trials (such as short exposure to a new drug) • sharing of anonymised individual patient biomarker and efficacy data from registration trials according to a predefined timing, thereby allowing data protection for only a limited period 	
Regulatory [65]	Solutions for efficiently bringing the most promising therapeutic solutions to patients (e.g. adaptive licencing and accelerated approval schemes) Better coordination of European Commission directorates (DG Santé, DG Research and so forth) to enable optimal access of patients to trials and treatments	Perpetuation of distinct mechanisms and policies within the European Commission leading to disjointed practices between the different directorates Lack of harmonisation of regulatory practices across Europe, despite EMA centralised procedures, as well as different evidentiary requirements between countries leading to slow uptake of innovations

ESTRO = European Society for Radiotherapy and Oncology; ESMO = European Society for Medical Oncology; EMA = European Medicines Agency.

in access to clinical trials between European countries. There is also a lack of large pan-European studies rather than regional or local studies with insufficient power to answer relevant clinical questions.

4.2. Regulatory approval

Processes to obtain regulatory approval for surgical procedures, radiation oncology and imaging techniques, and

their introduction into centres, vary considerably across Europe. As mentioned previously, the evidentiary requirements for these procedures are typically much lower than for medicines, often leaving it up to individual clinicians to evaluate them over time. The IDEAL framework mentioned previously calls for a much more transparent, evidence-based system whereby real-world evidence of the impact of new procedures is collected prospectively, with the aim of creating an up-to-date

database to guide more rapid and appropriate evaluation and uptake of these technologies over time [26–28].

In the field of medicines, significant strides have been made by regulatory agencies such as the EMA in recent years to accelerate the approval of potential innovations. For example, special allowances for orphan drugs and piloting of adaptive pathways by the EMA all allow for greater flexibility in regulatory requirements and more rapid access to new medicines by patients. The new EU Clinical Trial Regulation [29]—which aims to reduce some of the bureaucracy in clinical development programmes by requiring only one application via a single portal for trials conducted in several member states—may also be an important development. For paediatric cancers, the EU Paediatric Regulation has significantly changed the landscape for new drug development; however, significant unmet needs remain.

4.3. Reimbursement

Reimbursement or funding decisions for different components of cancer care are often divided among different decision bodies, who may base decisions on very different types of evidence. Different components of care are also evaluated and reimbursed separately. For example, targeted therapies, multi-target combinations thereof, as well as their companion diagnostics or biomarkers are often not evaluated jointly, and medicines given in hospital may be evaluated differently from those given in an outpatient setting. Finally, as has been mentioned previously, the level of evidence available to judge the value of medicines, diagnostics, imaging and surgical techniques may differ considerably, with physicians often asked to confirm the cost-effectiveness of medical diagnostics, for example, without necessarily having adequate training to do so.

A key issue is also that many reimbursement decisions focus solely on the immediate budget impact of a given intervention, so that even promising innovations are only looked at in terms of their immediate costs, with little consideration for their overall impact on healthcare utilisation in terms of reduced hospitalisations or long-term care, not to mention social costs such as fewer sick days due to a better tolerability profile or fewer complications. This is evident in the case of psychosocial support for patients, which is not reimbursed in many European countries. Even in countries where it is reimbursed, patients may not be reimbursed if they need to access psychosocial care outside of their local area or from private providers if these services are not available locally [30].

Another important limitation is that patients and their representatives are too seldom involved in HTA and other reimbursement decisions [31]. The inclusion of patient experience data captured during clinical trials would represent an important step forward from what is currently provided for HTA and other reimbursement submissions. This would contribute to providing a more

accurate and relevant account of the impact of new technologies on patients.

Finally, delays in reimbursement between countries are an ongoing concern, as they cause inequalities in access to care for patients across Europe. Looking specifically at medicines: in 1989, the European Commission set a maximum limit of 180 days [32] between the time a reimbursement dossier is submitted to the relevant national agency and market access is granted. Yet many countries continue to exceed this time limit, particularly in Central Eastern European countries (2008–2010 data) [33] and the United Kingdom. Reimbursement submissions are done on a country—and sometimes even a regional—level, with significant differences in access between and within countries as a result [9]. The recent work of the European Network for Health Technology Assessment (EUNetHTA) has helped in trying to increase collaboration between agencies and harmonise the evidence requirements across different HTA agencies, hopefully contributing to closer alignment when new medicines become available to patients in different countries. Needless to say, similar alignment is also needed for other aspects of cancer care.

4.4. Local uptake

There are known variations in the uptake of innovations across different care settings, often reflecting variations in the quality of care offered between specialised and non-specialised centres. Lack of specialisation may also increase the reliance on outdated or ineffective treatment approaches that could be replaced by more effective ones, thereby compromising the integration of innovative approaches into patient care.

A chosen approach in several countries has been to create designated ‘centres of excellence’ (or specialised centres). This centralisation may help to ensure consistency of quality across designated centres and allow for economies of scale in the purchase of imaging and other expensive equipment. Delivery of cancer care in specialist centres is particularly critical for rare cancers, as the small number of cases means that it is difficult for physicians to acquire sufficient experience and expertise in their treatment and care. To this end, Rare Cancers Europe has recommended that care for rare cancers be centralised in European Reference Networks (ERNs), of which three cover rare cancers (ERNs on rare adult solid tumours, blood disease and paediatric cancers).

With the development of ERNs and other centres of excellence, however, it will be important to make sure that centralisation of care does not create additional barriers to care for patients and that they work in close networks with local practitioners as part of a multidisciplinary care team adhering to the same protocols and guidelines. This networked model of care is already being implemented for children and adolescents with

cancer, and the European Society for Paediatric Oncology has defined the European Standards of Care for Children with Cancer [34].

A critical issue for centres of excellence is that they meet clear standards or essential requirements. For example, many hospitals that have so-called specialist cancer services are not organised into multidisciplinary units, as recommended by ECCO and other professional societies [35–37]. To this end, ECCO is currently developing essential standards to ensure a more consistent level of quality within designated specialised centres, looking specifically at colorectal cancer and bone and soft-tissue sarcomas [38,39].

An interesting example of the application of essential requirements is the designation of specialist breast units. Essential requirements were outlined by the European Society of Mastology in 2000 and updated in 2013 [40,41] and include a minimum caseload (>150 newly diagnosed cases per year), an audited database of quality indicators and research, multidisciplinary case management meetings, clear verbal and written patient information, and defined teaching and research plans [42].

Implementation of innovations may also be facilitated by the expansion of ‘coverage with evidence development’ (CED) schemes, which should be applied to all types of innovations, not just medicines. These schemes should be guided by health economic simulations in the early stages of research, and the availability of health economic expertise and knowledge to help guide implementation of CED schemes and data collection within each institution. Close collaboration with professional societies is also needed to ensure acceptance of innovations within practice guidelines.

5. Improving access to innovation in cancer care: potential solutions

Improving access—and overcoming some of the existing hurdles to access—to innovation will require a combination of levers at the political, system and individual hospital or clinic level. These are described in the following section.

5.1. Greater involvement of patients and caregivers in defining and assessing the value of innovation

- Comprehensive assessment of the impact of innovations on patients’ quality of life, risk/benefit balance and overall experience of care must be an integral part of the evaluation of any innovation, by using validated patient-reported outcomes and experience measures.
- Patients and their representatives should be involved early in the planning and conduct of research, as well as regulatory and HTA discussions related to innovation, to ensure that their perspectives guide the development and evaluation of innovations.

- Patient organisations should be supported to develop accessible information materials to inform the patient community about upcoming innovations with close collaboration from clinical specialists. They may act as powerful advocates for the integration of innovations into clinical practice and acceptability in the broad patient population.

5.2. A whole-system, whole-patient approach to guide investment in innovation

- Despite the continual focus on cost containment in healthcare, national governments should foster an innovation agenda by adopting a system-wide strategy for investment in innovation.
- This strategy should
 - be guided by identified patient needs, as measured by patient-relevant outcomes, with more research needed in close partnership with patient organisations to better understand unmet patient needs (clinical but also psychosocial and emotional), relevance and priorities in different cancers and where the need for innovation is greatest;
 - take a ‘whole-system’ as well as a ‘whole-patient’ approach, looking at what innovations may have the most impact across the entire care pathway, and moving away from siloed decisions on different types of care (e.g. medicines, medical devices, equipment, radiology and surgery).

5.3. More efficient and harmonised evaluation of innovation

- The evaluation of all innovations should be centralised and harmonised at a national or regional level, with a credible multidisciplinary group of stakeholders guiding decisions. This should ideally free individual hospitals or departments from having to make decisions about the value of innovations and create a more transparent evidence base on which investment in innovations may be made across different settings of care.
- Greater transparency in the evidence required for HTA and reimbursement decisions for all types of diagnostic procedures and care is also needed, including
 - closer alignment between these decisions and regulatory bodies to avoid unnecessary delays in access to patients;
 - where possible, greater alignment between countries in terms of HTA and reimbursement decisions, making greater use of EUNetHTA or similar entities for a coordinated approach between HTA agencies.

5.4. Investment in real-world data to guide investment in innovation

- Investment in well-designed registries, big data and other real-world data collection is key to assess the potential impact of innovations in clinical practice. Harmonisation of data sets both within and between countries is needed for us to be able to pool data from different sources. Real-world data may be used to guide:
 - reimbursement decisions, looking at the impact on costs and outcomes across the entire care pathway, and thereby

avoiding decisions based on immediate budget impact alone. Ideally, this process should be reviewed regularly, based on new data emerging over time;

- investment and integration of innovations into clinical practice;
- updating of clinical guidelines to reflect why a given intervention has not been integrated into the guideline based on evolving data on its effectiveness.
- Efforts to improve the potential for sharing of registry data across different countries are also needed; an example is the EMA project which is looking at making better use of existing patient registries and supporting the set-up of new ones on the basis of common protocols, scientific methods, structures, data sharing and transparency [43,44].

5.5. *Promotion of an innovation culture within the delivery of cancer care*

- The implementation of multidisciplinary teams (MDTs) across cancer care may compel individual specialists to look beyond their own area of expertise and take a whole-system approach to innovation, focussing on innovations that may make the greatest difference to patients, and adapt care pathways to integrate them into practice, and, together, ask: ‘How can we do things better?’ [35]
- MDTs may also provide an opportunity to continuously review clinical practice and stop wasting resources on things that have become inferior compared to updated standards and could be replaced by more efficient, innovative practices [35].
- New models of cancer care integrating primary care and secondary care need to be established to improve the quality of care, starting with an effective diagnosis.
- Continued educational efforts are also needed to disseminate existing guidelines to physicians and encourage their implementation, with specialist centres taking the lead in educational activities, on-site training, webinars or other information-sharing activities to keep everyone up-to-date on advances in care. European reference documents such as the European Guide on Quality National Cancer Control Plans [45] should also be considered.

5.6. *A pan-European vision on innovation (a vision and a will)*

- Finally, European cancer agencies may help build political will across different countries to embrace innovations. They may contribute to Europe-wide research—in true collaboration between the various Directorates of the European Commission—looking at how different healthcare systems may foster and evaluate innovations using common approaches and measures.
- These recommendations should be embedded in revised National Cancer Control Plans, which should be reviewed on a regular basis to take account of the continuously evolving care and treatment landscape.

6. Conclusions

Innovation requires investment, and this investment is needed if we are to continuously improve the lives and

hopes of cancer patients across Europe despite the financial pressures on our healthcare systems. Adopting a culture of innovation requires a multidisciplinary team approach, with the patient at the centre and an integral part of the team. It must take a whole-system and whole-patient perspective on cancer care, address unmet patient needs and be guided by high-quality real-world data, including patient-relevant outcomes and actual costs of care; these factors reflect the impact of any innovation in clinical practice. Similarly, patient organisations need to be actively engaged with other key stakeholders in the planning and evaluation of all aspects of cancer care.

This article is intended as a starting point to engage all relevant professionals involved in cancer care, as well as the patient and care community, in finding sustainable solutions to foster innovation within current and future cancer care. ECCO is committed to working with its member societies, patient organisations and the cancer community at large, to help identify sustainable ways to identify and integrate the most meaningful innovations into all aspects of cancer care. It is also committed to working with, and building on, professional educational efforts already being made by the European School of Oncology, ESTRO, European Society of Surgical Oncology and others to build multidisciplinary excellence in cancer care. It is our hope that this article may contribute to those efforts and be developed into a concrete action plan that ECCO and its member societies may follow to help contribute to sustainable, innovative cancer care for patients in years to come.

Conflict of interest statement

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References

- [1] Glunde K, Penet M-F, Jiang L, Jacobs MA, Bhujwalla ZM. Choline metabolism-based molecular diagnosis of cancer: an update. *Expert Rev Mol Diagn* 2015;15(6):735–47. <http://dx.doi.org/10.1586/14737159.2015.1039515>.
- [2] Hartwig W, Werner J, Jäger D, Debus J, Buechler MW. Improvement of surgical results for pancreatic cancer. *Lancet Oncol* 2013;14(11):e476–85. [http://dx.doi.org/10.1016/S1470-2045\(13\)70172-4](http://dx.doi.org/10.1016/S1470-2045(13)70172-4).
- [3] Hashizume M, Tsugawa K. Robotic surgery and cancer: the present state, problems and future vision. *Jpn J Clin Oncol* 2004; 34(5):227–37 [published Online First: 2004/07/03].
- [4] MacFarlane JK, Ryall RD, RJ H. Mesorectal excision for rectal cancer. *Lancet* 1993;341:457–60.
- [5] Gupta V, McGunigal M, Prasad-Hayes M, Kalir T, Liu J. Adjuvant radiation therapy is associated with improved overall survival in high-intermediate risk stage I endometrial cancer: a national cancer data base analysis. *Gynecol Oncol* 2016. <http://dx.doi.org/10.1016/j.ygyno.2016.10.028>.
- [6] Purdy JA. 3D treatment planning and intensity-modulated radiation therapy. *Oncology (Williston Park, NY)* 1999;13(10 Suppl 5):155–68 [published Online First: 1999/11/07].
- [7] Gonzalez de Castro D, Clarke PA, Al-Lazikani B, Workman P. Personalized cancer medicine: molecular diagnostics, predictive biomarkers, and drug resistance. *Clin Pharmacol Ther* 2013;93(3): 252–9. <http://dx.doi.org/10.1038/clpt.2012.237>.
- [8] Gerber DE. Targeted therapies: a new generation of cancer treatments. *Am Fam Phys* 2008;77(3):311–9.
- [9] Mirivsky BJ, Shulman LN, Abernethy AP. Importance of health information technology, electronic health records, and continuously aggregating data to comparative effectiveness research and learning health care. *J Clin Oncol* 2012;30(34):4243–8. <http://dx.doi.org/10.1200/jco.2012.42.8011>.
- [10] Cherny N, S R, Torode J, Saar M, Eniu A. ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe. *Ann Oncol* 2016;27:1423–43.
- [11] Jönsson B, Hofmarcher T, Lindgren P, Wilking N. Comparator report on patient access to cancer medicines in Europe revisited. IHE Report. Lund: IHE; 2016.
- [12] Directorate General for Internal policies. EU options for improving access to medicines. Study for the ENVI Committee: European Parliament Policy department Economic and Scientific Policy A. 2016.
- [13] Lawler M, Apostolidis K, Banks I, Florindi F, Militaru M, Price R, on Behalf of the Europe of Disparities in Cancer Working Group. Challenging the Europe of Disparities in Cancer – a framework for improving survival and better quality of life for European cancer patients. On behalf of the Europe of Disparities in Cancer Working Group; 2015.
- [14] Sullivan R, Peppercorn J, Sikora K, Zalberg J, Meropol NJ, Amir E, et al. Delivering affordable cancer care in high-income countries. *Lancet Oncol* 2011;12(10):933–80. [http://dx.doi.org/10.1016/S1470-2045\(11\)70141-3](http://dx.doi.org/10.1016/S1470-2045(11)70141-3).
- [15] Thomas R, Callahan R, Bartlett R, Geissler J. Delivering affordable cancer care: a value challenge to health systems. In: *World Innovation Summit for Health*, editor. WISH Highlights. Institute of Global Health Innovation, Imperial College London; 2015.
- [16] Cavalli F. Tackling cancer: time for a global response. *Lancet* 2016;387:e13–4.
- [17] Wagstaff A. Five steps to putting innovation at the heart of cancer care. *Cancer World* 2014. Available from: http://www.cancerworld.org/pdf/3437_pagina_25_33_Systems_Services.pdf [Accessed 7 April 2016].
- [18] Merriam-Webster Dictionary Online. Innovation.
- [19] Oxford Dictionaries Online. Innovation.
- [20] Cherny N, Sullivan R, Dafni U, Kerst JM, Sobrero A, Zielinski C, et al. A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS). *Ann Oncol* 2015;26:1547–73.
- [21] Schnipper LE, Davidson NE, Wollins DS, Blayney DW, Dicker AP, Ganz PA, et al. Updating the American Society of Clinical Oncology value framework: revisions and reflections in response to comments received. *J Clin Oncol* 2016;34(24):2925–34. <http://dx.doi.org/10.1200/JCO.2016.68.2518>.
- [22] Institute for Clinical and Economic Review. ICER value assessment framework. 2016. Available from: <https://icer-review.org/methodology/icers-methods/icer-value-assessment-framework/> [Accessed 27 October 2016].
- [23] Schnipper L, B A. New frameworks to assess value of cancer care: strengths and limitations. *Oncologist* 2016;21:654–8.
- [24] Network. NCC. Available at: <http://www.nccn.org/evidenceblocks/pdf>. [Accessed 20 May 2016].
- [25] Schilsky RL. Moving from evaluation to value in cancer care. *Clin Cancer Res* 2015;21(5):947–9. <http://dx.doi.org/10.1158/1078-0432.ccr-14-2533> [published Online First: 2014/10/23].
- [26] McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, et al. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009;374(9695):1105–12. [http://dx.doi.org/10.1016/S0140-6736\(09\)61116-8](http://dx.doi.org/10.1016/S0140-6736(09)61116-8) [published Online First: 2009/09/29].
- [27] Pennell CP, Hirst A, Sedrakyan A, McCulloch PG. Adapting the IDEAL Framework and Recommendations for medical device evaluation: a modified Delphi survey. *Int J Surg* 2016;28:141–8. <http://dx.doi.org/10.1016/j.ijsu.2016.01.082> [published Online First: 2016/02/16].
- [28] Sedrakyan A, Campbell B, Merino JG, Kuntz R, Hirst A, McCulloch P. IDEAL-D: a rational framework for evaluating and regulating the use of medical devices. *BMJ* 2016;353:i2372. <http://dx.doi.org/10.1136/bmj.i2372> [published Online First: 2016/06/11].
- [29] European Parliament. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. In: Union CotE, editor; 2014.
- [30] Travado L, Reis JC, Watson M, Borrás J. Psychosocial oncology care resources in Europe: a study under the European Partnership for Action Against Cancer (EPAAC). *Psychooncology* 2015. <http://dx.doi.org/10.1002/pon.4044>.
- [31] European Patients' Forum. Patient involvement in health technology assessment in Europe – an interim report on EPF survey with HTA agencies. EPF Survey. 2013.
- [32] European Commission. Council directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. In: Commission E, editor; 1989. 89/105/EEC.

- [33] European Federation of Pharmaceutical Industries and Associations. Patients' W.A.I.T. Indicator. Market Access Delays. 2010.
- [34] Kowalczyk J, Samardakiewicz M, Pritchard-Jones K, Ladenstein R, Essiaf S, Fitzgerald E, et al. European survey on standards of care in paediatric oncology centres. *Eur J Cancer* 2016;61(11–19).
- [35] European Partnership Action Against Cancer consensus group, Borras JM, Albrecht T, Audisio R, Briers E, Casali P, Esperou H, et al. Policy statement on multidisciplinary cancer care. *Eur J Cancer* 2014;50(3):475–80. <http://dx.doi.org/10.1016/j.ejca.2013.11.012>.
- [36] Epstein NE. Multidisciplinary in-hospital teams improve patient outcomes: a review. *Surg Neurol Int* 2014;5(Suppl 7):S295–303. <http://dx.doi.org/10.4103/2152-7806.139612>.
- [37] Prades J, Remue E, van Hoof E, Borras JM. Is it worth reorganising cancer services on the basis of multidisciplinary teams (MDTs)? A systematic review of the objectives and organisation of MDTs and their impact on patient outcomes. *Health Policy* 2015;119(4):464–74. <http://dx.doi.org/10.1016/j.healthpol.2014.09.006>.
- [38] Andritsch E, Beishon M, Bielack S, Bonvalot S, Casali P, Crul M, et al. ECCO essential requirements for quality cancer care: soft tissue sarcoma in adults and bone sarcoma. A critical review. *Crit Rev Oncol Hematol* 2017;110:94–105.
- [39] Beets G, Sebag-Montefiore D, Andritsch E, Arnold D, Beishon M, Crul M, et al. ECCO essential requirements for quality cancer care: colorectal cancer. A critical review. *Crit Rev Oncol Hematol* 2017;110:81–93.
- [40] Blamey R, Cataliotti L. The requirements of a specialist breast unit. *Eur J Cancer* 2000;36:2288–93.
- [41] Wilson AR, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al. The requirements of a specialist Breast Centre. *Eur J Cancer* 2013;49(17):3579–87. <http://dx.doi.org/10.1016/j.ejca.2013.07.017> [published Online First: 2013/08/24].
- [42] European CanCer Organisation. European breast units manifesto 2016. 2016 [updated 11 March 2016; cited 2016 27 October]. Available from: <http://www.ecco-org.eu/Events/EBCC10/European-Breast-Units-Manifesto> [Accessed 27 October 2016].
- [43] European Medicines Agency. Collecting high-quality information on medicines through patient registries. Initiative aims to support use of existing registries to collect information on medicines in clinical use and support benefit-risk evaluation. 2015.
- [44] European Medicines Agency. Initiative for patient registries: strategy and pilot phase. In: *Inspections and Human Medicines Pharmacovigilance Division, editor*; 2015. London, United Kingdom.
- [45] Albrecht T, Martin-Moreno JM, Jelenc M, Gorgojo L, Harris M. European guide for quality national cancer control programmes. National Institute of Public Health; 2015.
- [46] Macmillan Cancer Support. Cancer clinical nurse specialists. Impact briefs. 2014.
- [47] European Oncology Nursing Society (EONS). EONS position statement: the role of nurses in cancer care. Available from: <http://www.cancernurse.eu/advocacy/positionstatementcancercare.html2016>.
- [48] Tot T, Viale G, Rutgers E, Bergsten-Nordstrom E, Costa A. Optimal breast cancer pathology manifesto. *Eur J Cancer* 2015;51(16):2285–8. <http://dx.doi.org/10.1016/j.ejca.2015.06.127> [published Online First: 2015/08/19].
- [49] Jain KK. Personalised medicine for cancer: from drug development into clinical practice. *Expert Opin Pharmacother* 2005;6(9):1463–76. <http://dx.doi.org/10.1517/14656566.6.9.1463>.
- [50] Moran MS, Schnitt SJ, Giuliano AE, Harris JR, Khan SA, Horton J, et al. Society of Surgical Oncology–American Society for Radiation Oncology Consensus Guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer. *Int J Radiat Oncol Biol Phys* 2014;88(3):553–64. <http://dx.doi.org/10.1016/j.ijrobp.2013.11.012>.
- [51] Fernández-Hevia M, Delgado S, Castells A, Tasende M, Momblan D, Díaz del Gobbo G, et al. Transanal total mesorectal excision in rectal cancer: short-term outcomes in comparison with laparoscopic surgery. *Ann Surg* 2015;261(2):221–7. <http://dx.doi.org/10.1097/sla.0000000000000865>.
- [52] Heald R, Husband E, Ryall R. The mesorectum in rectal cancer surgery—the clue to pelvic recurrence? *Br J Surg* 1982;69(10):613–6.
- [53] Marshall JL, Cartwright TH, Berry CA, Stowell S, Miller SC. Implementation of a performance improvement initiative in colorectal cancer care. *J Oncol Pract* 2012;8(5):309–14. <http://dx.doi.org/10.1200/JOP.2011.000461>.
- [54] Owusu C, Berger NA. Comprehensive geriatric assessment in the older cancer patient: coming of age in clinical cancer care. *Clin Pract* 2014;11(6):749–62. <http://dx.doi.org/10.2217/cpr.14.72>.
- [55] Vassal G, Rousseau R, Blanc P, Moreno L, Bode G, Schwoch S. Creating a unique, multi-stakeholder Paediatric Oncology Platform to improve drug development for children and adolescents with cancer. *Eur J Cancer* 2015;51:218–24.
- [56] Vassal G, Fitzgerald E, Schrappe M, Arnold F, Kowalczyk J, Walker D. Challenges for children and adolescents with cancer in Europe: the SIOP-Europe agenda. *Pediatr Blood Cancer* 2014;61:1551–7.
- [57] Salas-Vega S, Haimann A, Mossialos E. Big data and health care: challenges and opportunities for coordinated policy development in the EU. *Health Syst Reform* 2015;1(4):285–300. <http://dx.doi.org/10.1080/23288604.2015.1091538>.
- [58] Garrison LP, Neumann PJ, Erickson P, Marshall D, Mullins CD. Using real-world data for coverage and payment decisions: the ISPOR real-world data task force report. *Value Health* 2007;10(5):326–35. <http://dx.doi.org/10.1111/j.1524-4733.2007.00186.x>.
- [59] Larsen MB, Jensen H, Hansen RP, Olesen F, Vedsted P. Identification of patients with incident cancers using administrative registry data. *Dan Med J* 2014;61.
- [60] Christensen KG, Fenger-Gron M, Flarup KR, Vedsted P. Use of general practice, diagnostic investigations and hospital services before and after cancer diagnosis—a population-based nationwide registry study of 127,000 incident adult cancer patients. *BMC Health Serv Res* 2012;12. <http://dx.doi.org/10.1186/1472-6963-12-224>.
- [61] Coleman MP, Forman D, Bryant H, Butler J, Rachet B, Maringe C, et al. Cancer survival in Australia, Canada, Denmark, Norway, Sweden, and the UK, 1995–2007 (the International Cancer Benchmarking Partnership): an analysis of population-based cancer registry data. *Lancet* 2011;377. [http://dx.doi.org/10.1016/s0140-6736\(10\)62231-3](http://dx.doi.org/10.1016/s0140-6736(10)62231-3).
- [62] Gjerstorff ML. The Danish cancer registry. *Scand J Public Health* 2011;39. <http://dx.doi.org/10.1177/1403494810393562>.
- [63] El Turabi A, Abel GA, Roland M, Lyratzopoulos G. Variation in reported experience of involvement in cancer treatment decision making: evidence from the National Cancer Patient Experience Survey. *Br J cancer* 2013;109(3):780–7.
- [64] Coulter A, Locock L, Ziebland S, Calabrese J. Collecting data on patient experience is not enough: they must be used to improve care. *BMJ* 2014;348:g2225. <http://dx.doi.org/10.1136/bmj.g2225>.
- [65] Schulthess D, Baird LG, Trusheim M, Unger TF, Lumpkin M, Hoos A, et al. Medicines adaptive pathways to patients (MAPPs): a story of international collaboration leading to implementation. *Ther Innov Regul Sci* 2015. <http://dx.doi.org/10.1177/2168479015618697>.